AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions and listings of claims in this application:

1. (Currently Amended) A gel formulation for the transdermal or transmucosal administration of an active agent comprising:

at least one active agent of ~~a hormone, provided when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount and further provided that, when the active agent is~~ testosterone~~, the testosterone is the sole active agent and it~~ which is present in an amount of about 1% or less by weight of the formulation;

a gelling agent; and

a delivery vehicle comprising an alkanol, a polyalcohol and a permeation enhancer of a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces;

wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during use of the formulation, and

wherein the alkanol is present in an amount between 5 to 80% by weight of the delivery vehicle, the polyalcohol is present in an amount between 1% to 15% by weight of the delivery vehicle, and the permeation enhancer is present in an amount between 0.2% to 15% by weight of the delivery vehicle so that the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

Claim 2. (Cancelled)

3. (Currently Amended) The formulation of claim 1, wherein ~~the active agent is estradiol present in an amount between 0.01% to 2% of the formulation;~~ the alkanol is present in

an amount between 20 to 65% of the formulation; the polyalcohol is propylene glycol; the permeation enhancer is diethylene glycol monoethyl ether; the gelling agent is present in an amount of between 0.05% to 4% of the formulation, and the formulation further comprises a neutralizing agent present in an amount between 0.05% and 1% of the formulation, and water present in an amount between 20% to 65% of the formulation.

4. (Original) The formulation of claim 3, further comprising a sequestering agent.

5. (Previously Presented) The formulation of claim 1, wherein the alkanol is in combination with water to form a hydroalcoholic mixture, the hydroalcoholic mixture is present in an amount of between 40 to 98% by weight of the delivery vehicle, and the alkanol is present in an amount of between 5% to 80% by weight of the mixture, and the water is present in an amount of between 20% to 95% by weight of the mixture.

6. (Previously Presented) The formulation of claim 1, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 2:1 to 1:1 and the total amount of polyalcohol and permeation enhancer is not more than 15% of the formulation.

7. (Previously Presented) The formulation of claim 1, wherein the alkanol is a C_2 to C_4 alcohol selected from the group consisting of ethanol, isopropanol, and n-propanol, the polyalcohol is propylene glycol or polypropylene glycol, and the permeation enhancer is a monoalkyl ether of diethylene glycol.

Claims 8. to 10. (Cancelled)

11. (Previously Presented) The formulation of claim 1, wherein the formulation further comprises at least one of a neutralizing agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, or emollient.

Claim 12. (Cancelled)

13. (Previously Presented) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the gel formulation of claim 1 for treating at least one symptom of the hormonal disorder selected from the group consisting of hypogonadism, female menopausal symptoms, female sexual dysfunction, hypoactive sexual desire disorder, and adrenal insufficiency, and wherein the administration of the formulation decreases the frequency of at least one clinical symptom of the hormonal disorder.

Claim 14. to 16. (Cancelled)

17. (Currently Amended) The method of claim 13 ~~16~~, wherein the subject is a female subject, ~~the active agent is testosterone~~ and the therapeutically effective dosage of testosterone is from about 2.2 milligrams to about 0.88 grams each 24 hours.

18. (Currently Amended) The method of claim 13 ~~16~~, wherein the subject is a female subject, ~~the active agent is testosterone,~~ and further wherein the method increases serum levels of the testosterone to about 142 nanograms per deciliter.

19. (Currently Amended) The method of claim 13 ~~16~~, wherein the subject is a female subject~~, the active agent is testosterone~~, and further wherein the method increases serum levels of the testosterone to about 17 picograms per milliliter.

Claims 20. to 28. (Canceled)

29. (Currently Amended) The method of claim 13, wherein a male subject is treated for hypogonadism~~, and the active agent includes at least one androgen~~.

Claims 30. to 36. (Cancelled)

37. (Currently Amended) A formulation for the transdermal or transmucosal administration of an active agent consisting essentially of:

at least one active agent of ~~a hormone, provided when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount and further provided that, when the active agent is~~ testosterone~~, the testosterone is the sole active agent and it~~ which is present in an amount of about 1% or less by weight of the formulation;

a gelling agent; and

a delivery vehicle comprising an alkanol, a polyalcohol and a permeation enhancer of a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces;

wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids, and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during use of the formulation; and

wherein the alkanol is present in an amount between 5 to 80% by weight of the delivery vehicle, the polyalcohol is present in an amount between 1% to 15% by weight of the delivery vehicle, and the permeation enhancer is present in an amount between 0.2% to 15% by weight of the delivery vehicle so that the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

Claims 38 and 39. (Cancelled)

40. (Previously Presented) The formulation of claim 37, wherein the alkanol is in combination with water to form a hydroalcoholic mixture, the hydroalcoholic mixture is present in an amount of between about 40 to 98% by weight of the delivery vehicle, and the alkanol is present in an amount of between 5% to 80% by weight of the mixture, and the water is present in an amount of between 20% to 95% by weight of the mixture .

41. (Previously Presented) The formulation of claim 37, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 2:1 to 1:1 and the total amount of polyalcohol and permeation enhancer is not more than 15% of the formulation.

42. (Previously Presented) The formulation of claim 37, wherein the alkanol is a C_2 to C_4 alcohol selected from the group consisting of ethanol, isopropanol, and n-propanol, and the polyalcohol is propylene glycol or polypropylene glycol.

Claims 43. to 45. (Cancelled)

46. (Previously Presented) The formulation of claim 37, wherein the formulation further comprises at least one of a neutralizing agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, or emollient.

47. (Original) The formulation of claim 37, wherein the formulation is in the form of a gel, lotion, cream, spray, aerosol, ointment, emulsion, suspension, liposomal system, lacquer, patch, bandage, or occlusive dressing.

Claims 48. to 55. (Cancelled)

56. (Previously Presented) A kit for treating a subject for increasing serum levels of a hormone in a subject comprising:

a gel formulation according to claim 1; and

a container that retains the formulation and includes a dispenser for releasing or applying a predetermined dosage or volume of the formulation upon demand.

57. (Original) The kit of claim 56, wherein the dispenser automatically releases the predetermined dosage or volume upon activation by a user.

58. (Original) The kit of claim 56, wherein the dispenser is a pump.

Claim 59. (Cancelled)

60. (Currently Amended) A ~~gel~~ formulation for the transdermal or transmucosal administration of an active agent for treating a hormonal disorder in a subject comprising:

at least one active agent of a hormone which is effective for treating at least one symptom of the hormonal disorder and in an amount effective for that purpose, ~~provided that when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount, and further provided that, when~~ wherein the active agent is testosterone~~, the testosterone is the sole active agent and it~~ which is present in an amount of about 1% or less by weight of the formulation;

~~a gelling agent;~~ and

a delivery vehicle comprising an alkanol, propylene glycol, and a permeation enhancer of a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces, wherein the alkanol is present in an amount between 20 to 65% by weight of the delivery vehicle, the propylene glycol is present in an amount between 1% to 15% by weight of the delivery vehicle, and the permeation enhancer is present in an amount between 0.2% to 15% by weight of the delivery vehicle, with the propylene glycol and permeation enhancer being present in a weight ratio of 2:1 to 1:1, and with the alkanol being ethanol, isopropanol, or n-propanol, so that the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces; and

wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during use of the formulation and the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

61. (Currently Amended) A kit for treating a subject for increasing serum levels of an active agent in a subject comprising:

~~a gel~~ the formulation according to claim 60; and

a container that retains the formulation and includes a dispenser for releasing or applying a predetermined dosage or volume of the formulation upon demand.

62. (Previously Presented) The kit of claim 61, wherein the dispenser automatically releases the predetermined dosage or volume upon activation by a user.

63. (Previously Presented) The kit of claim 61, wherein the dispenser is a pump.

Claim 64. to 66. (Cancelled)

67. (Currently Amended) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the gel formulation of claim 37 ~~66~~.

68. (Currently Amended) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the ~~gel~~ formulation of claim 60.

69. (New) The formulation of claim 1, wherein the testosterone is present in an amount of about 1% by weight, the gelling agent is present in an amount of about 1.2% by weight, the alkanol is ethanol in an amount of about 47.5% by weight, the polyalcohol is propylene glycol in an amount of 6% by weight, and the permeation enhancer is a monoethyl ether of diethylene glycol in an amount of about 5% by weight.

70. (New) The method of claim 13, wherein the testosterone is present in an amount of about 1% by weight, the gelling agent is present in an amount of about 1.2% by weight, the alkanol is ethanol in an amount of about 47.5% by weight, the polyalcohol is propylene glycol in an amount of 6% by weight, and the permeation enhancer is a monoethyl ether of diethylene glycol in an amount of about 5% by weight.

71. (New) The formulation of claim 37, wherein the testosterone is present in an amount of about 1% by weight, the gelling agent is present in an amount of about 1.2% by weight, the alkanol is ethanol in an amount of about 47.5% by weight, the polyalcohol is

propylene glycol in an amount of 6% by weight, and the permeation enhancer is a monoethyl ether of diethylene glycol in an amount of about 5% by weight.

72. (New) The formulation of claim 60, wherein the testosterone is present in an amount of about 1% by weight, the alkanol is ethanol in an amount of about 47.5% by weight, the polyalcohol is propylene glycol in an amount of 6% by weight, and the permeation enhancer is a monoethyl ether of diethylene glycol in an amount of about 5% by weight.